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14. ABSTRACT Substance use disorders (SUD) and Posttraumatic stress disorder (PTSD) are some of the most prominent psychiatric disorders among Service Members (SMs), including the Operation Enduring Freedom and Operation Iraqi Freedom (OEF/OIF) cohort. These disorders sometimes go untreated due to SMs lack of awareness, access to care, or stigma about accessing care. Seeking Safety (SS) has been established as an effective model for co-occurring SUD/PTSD. The purpose of this study is to evaluate the SS manual and Adherence Scale for implementation in a military setting. We have made substantial progress in moving the project forward, but as yet there are no research findings to report.				
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INTRODUCTION

Substance use disorders (SUD) and Posttraumatic stress disorder (PTSD) are some of the most prominent psychiatric disorders among Service Members (SMs), including the Operation Enduring Freedom and Operation Iraqi Freedom (OEF/OIF) cohort. These disorders sometimes go untreated due to SMs lack of awareness, access to care, or stigma about accessing care. Seeking Safety (SS) has been established as an effective model for co-occurring SUD/PTSD. The purpose of this study is to evaluate the SS manual and Adherence Scale for implementation in a military setting. We hypothesize that the Seeking Safety manual and Adherence Scale can be successfully used in the military setting, with “success” defined as 80% or higher satisfaction and feasibility on this project by at least 80% of participants.

BODY

To best describe the research accomplishments associated with each task outlined in the approved Statement of Work, we include the approved Statement of Work for the first 12 months of this project in italics below. Following each task listed in the Statement of Work, we provide a description of our progress on that task.

STATEMENT OF WORK

Task 1: Study startup (months 1-6)
Apply for human subjects approval at each site

Human subjects approval updates

WRNMMC

The Walter Reed National Military Medical Center (WRNMMC) IRB initially approved the study as a process improvement project on 23 May 2011. However, upon a secondary review of the study protocol by the U.S. Army Medical Research and Materiel Command, Office of Research Protections, Human Research Protection Office (HRPO), it was determined to constitute research. The study was subsequently approved as a research project on 24 April 2012 by the WRNMMC IRB.

The WRNMMC IRB approved study documents were forwarded to HRPO on 15 August 2012 for review. In addition, HRPO granted the project a No-Cost Extension for the study to continue through 31 July 2013.

A CRADA/SOW was generated for both sites, WRNMMC and Tripler Army Medical Center (TAMC), related to the study in early July 2012. The document is currently under review by the IRB legal departments at both sites prior to signature collection. Attempts to obtain an estimated time for completion have been unsuccessful.

Tripler

IRB Site Specific proposal was submitted and is currently under TAMC IRB review. DCI staff has coordinated closely with AI, Dr. Rebecca Beardsley, and Research Assistant, Stephanie Southard from WRNMMC, to complete any IRB forms needed for review by

TAMC IRB. Dr. Victoria Garshnek, DCI at TAMC, has coordinated with WRNMMC IRB staff regarding the multisite study and the relevant IRB forms. They have also assisted in coordinating the CRADA and IAIR forms.

Treatment Innovations (TI)

TI was informed by HRPO in July that it needed to obtain independent IRB approval. The PI applied for IRB approval (for data analysis only, as no data collection occurs at TI) from the New England IRB, and obtained that.

Please note that we have been doing everything possible to obtain IRB approval (despite the many lengthy delays due to IRB staff's workload burdens and sometimes confusing information as to what was needed, especially for the multi-site nature of this project). We are confident that we are close and with the no-cost extension will be able to attain all study aims. See also last year's report on the IRB issues faced in the prior year.

Finally, please note that in last year's annual report, we stated that we were considering adding Fort Belvoir as a study site, but this year we decided not to as this would just complicate the already significant IRB hurdles and likely delay the project even further.

Establish regular conference calls with sites

We have established regular calls with each site to discuss progress on the project and ongoing tasks that need to be completed. All sites are in continual communication regarding other study aspects, with ongoing emails and conference calls as needed. Also, Dr. Najavits has held one conference call with study clinicians at WRNMMC to as part of the development of the military monograph and is currently scheduling another, as well as one with Tripler.

Train staff as needed

WRNMMC

There are no staffing updates to report at WRNMMC.

Tripler

Changes to staff include the addition of a new PI: Dr. Benjamin O'Brien, Staff psychologist at Schofield Army Barracks; and a new AI: Dr. Stetz, Director of Research/Tripler Psychology Dept. The project also has a new Research Assistant: Beth Sauer who is psychology graduate student from University of Hawaii, Manoa. Ms. Sauer replaces Heather Jablonski, MSW, who was hired for Tripler starting 1/12, but after a few months determined that she wanted a higher-level social work position, and thus we hired Ms. Sauer.

Fort Jackson

This year, we hired a research assistant for Fort Jackson (Pamela Smith). Ms. Smith worked on the study only a few months as we then dropped Fort Jackson as a site due

to a change in our site PI's role there (no longer having oversight of the substance abuse treatment clinicians, which were the key pool of clinicians for our study).

TI

At TI, John Lung, the RA, has received training from our study statistician to learn basic analyses and data integrity procedures. Dr. Nicole Capezza went on maternity leave, came back at partial time, and then decided to obtain a job closer to her home given her new baby. Thus, the PI has hired a new postdoctoral clinical psychology trainee, Dr. Melissa Anderson, who is starting 9/1/12 at half-time. TI also made use of several administrative people (Daniel Kilburn, Lindsay Neagle, and Raymond Martin), all of whom are providing assistance on various other TI projects and who have been able to do as-needed efforts for this project at low cost.

Overall note: funding of study research assistants is primarily via the PI's other DoD grant that is also a study of SS ([W81XWH1020074](#)), and thus we are able to leverage the RAs' time to work on this study as many of the RA tasks converge for the two project (e.g., use of the same logs, interactions with clinicians, etc.)

With regard to training of study clinicians, originally Dr. Reeder was the SS consultant/trainer for WRNMMC and Dr. Schmitz for Tripler and Fort Jackson. However, the PI decided it is more efficient to have Dr. Schmitz work with all sites for better coordination. She took on that role across all sites in winter 2012, and that has allowed us to make major progress in moving forward with our scientific aim of having all clinicians well-versed in SS, to aid preparation of the military monograph. Her report for the year on this is as follows.

1. WRAMC has a total of 15 clinicians who participated in Seeking Safety consultation from 8/1/11 – 7/31/12; 6 clinicians from Addiction Treatment Services and 9 clinicians from Psychiatric Continuity Services. 3 clinicians completed certification in SS. Moreover, 29 clinicians have been trained in Seeking Safety since May 2011; however, only ten clinicians remain active study participants due to site staffing limitations and time constraints. New employees, interns, and students are encouraged to participate in the study. Three clinicians have been certified in Seeking Safety; however, two certified clinicians left WRNMMC for other opportunities. Approximately twelve group mentoring calls have been held since July 2011. Three clinicians have had individual mentoring sessions since June 2012. The overall study PI, Dr. Lisa Najavits, has spoken with the clinicians in person and by phone to obtain study feedback data for use in the construction of the military monograph.
2. Dr. Martha Schmitz became a Seeking Safety consultant for WRAMC in May 2012. Since that time, she has held 3 group consultation calls (1 with Addiction Treatment Services; 2 with Psychiatric Continuity Services). She has also reviewed 3 tapes and has held 3 individual mentoring calls with clinicians from Psychiatric Continuity Services. Dr. Najavits reviews tapes as needed among those that are sent.
3. Dr. Schmitz has made several contributions to the project. She helped develop a log to track clinicians' progress in learning the model, conducting sessions, and

completing necessary paperwork (e.g., Seeking Safety Format Checklist and Brief Adherence Scale). She suggested that we hold monthly calls with RA's and PI's to discuss implementation issues. She revised the consultation process by offering individual feedback sessions to clinicians to provide clear and specific narrative feedback about their sessions. Clinicians endorsed these calls as tremendously helpful for understanding how to implement the model. Through this process, Dr. Schmitz discovered that clinicians were unclear about some of the basic concepts of the treatment. Dr. Schmitz was able to clear up their misconceptions and to communicate this information with the study PIs. Thus, Dr. Schmitz's involvement as a consultant has allowed for greater quality of SS implementation on this project.

Develop data entry procedures for on-going data entry

We continue to use our electronic method of data collection that is acceptable to the military sites' IRBs (using Adobe Acrobat), which allows us to eliminate hand entered data entry procedures, as all measures for patients, clinicians and study staff are filled out via computer and saved electronically.

Set up systems for tracking data progress

We have developed new study logs for clinicians to aid their progress (see above in section Training). We also have available our other existing tracking logs for available use.

Set up standard operating procedures

We have strong and efficient systems in place for all study tasks. All study personnel have contributed to these efforts.

Begin the initial Delphi procedure with our consultant team

We have not started the Delphi procedure. We have focused instead on obtaining information from study clinicians, site PIs and AIs, and Dr. Schmitz (the study trainer/consultant). These latter efforts are much more informative at this phase of our progress. The study clinicians have been continually adding to the the General Feedback log to record any comments they have regarding conducting the SS therapy. Also, we have focused our efforts toward the military monograph (see that section below).

Task 2: Adapt the SS manual and adherence scale for military use (months 6-22)

Months 7-8: obtain T1 assessment on the first half of the sample of clients and clinicians; then provide them with SS materials.

Months 9-10: create the initial draft of the military SS monograph and adherence scale (based on feedback obtained in prior months).

Months 10-11: Obtain T2 assessment from first half of sample.

Months 11-13: obtain T1 assessment from the second half of the sample; and continue Delphi procedure with consultants.

Military monograph

The PI has held one conference call with study clinicians at WRNMMC to as part of the development of the military monograph and is currently scheduling another, as well as one with Tripler.

Also, in 2013 the PI will be guest editor of a special issue on complex trauma in *Journal of Clinical Psychology: In Session*. She scheduled a conference call with PIs from the sites for August, 2012, and one idea that is being considered is to have the military monograph be an article in that special issue. That would allow for greater circulation of it, as well as provide an initial publication from the project in a timely way.

At WRNMMC, quantitative data, generated by the study as a process improvement project, is currently being analyzed at WRNMMC while the CRADA/SOW is being reviewed. The approval of this document will allow study data to be sent to the biostatistician and qualitative data expert at Treatment Innovations for review (which of course will be sent only once we are granted approval for this by all relevant IRBs and with HRPO oversight).

Data collection

No sites have nor will collect any data that is not IRB-approved and HRPO-approved. However, as noted in our prior annual report, the determination of the IRB at WRAMC was that this project was a Quality Improvement Project (QIP) and not a Research Project. Thus, we have been able to collect data on that basis, with the idea that this allows us to at least obtain informative information for the scientific goals of this study.

At WRNMMC, as part of the QIP, over 150 patients have attended Seeking Safety sessions since May 2011. Feedback on at least one individual Seeking Safety topic has been received from over 83 clients and 29 clinicians. Twenty-five clients have completed phase one of the study by receiving 8 or more topics in either individual or group sessions. Ten clinicians had completed phase one of the study by June 2012 (due to either completion of at least 20 topics or termination of employment). Data collected from phase one is being analyzed by WRNMMC while awaiting approval of the CRADA/SOW.

Scientific Achievements

New advisory board activities by the PI:

10/11	NIDA, SBIR Special Emphasis Panel, Scientific Review Group
3/12	Acting Chair, NIDA, SBIR Special Emphasis Panel, Scientific Review Group
2012-pres.	Expert Advisory Panel, Insitute on Trauma and Trauma-Informed Care, University at Buffalo—The State University of New York

- 2012-pres. Advisory Board, Center for Gambling Research at the University of Georgia, Athens, GA
- 2012-pres. Editorial Board, Journal of Traumatic Stress

New and/or ongoing grants by the PI (other than the current one):

2011-2012	VA (HSR&D)	Development of a PTSD/SUD program- level assessment / PI (\$99,997 direct)
2010-2012	DoD	Seeking Safety Therapy for PTSD, TBI, and Substance Use Disorder (\$737,734 total) grant #PT090554
2011-2013	VA (CSR&D)	Pilot study of an integrated exposure-based model for PTSD and SUD / Co-PI (Co-PI Krinsley) (\$250,726 direct)
2011-2015	VA (HSR&D)	MISSION-Vet HUD VASH Implementation Study / Co-I (PI: Smelson) (\$1,098,800 direct)
2012-2013	VA (HSR&D)	Assessment of suicide, violence, and related high-risk behaviors in veterans / PI (\$99,996)

New professional publications by the PI completed since the prior annual report

Capezza, N., & Najavits, L. M. (2012). Trauma counseling in substance abuse treatment facilities: Rates and characteristics of over 10,000 programs. *Psychiatric Services*, 63(4), 390-394.

Ellison, M.L., Mueller, L., Smelson, D., Corrigan, P., Bokhour, B., Torres-Stone, R., **Najavits, L.M.**, Vessella, J., & Drebing, C. (2012) Supporting the Education Goals of Post 9/11 Veterans with self-reported PTSD symptoms: A needs assessment, *Psychiatric Rehabilitation Journal*, 35(3), 209-217.

Ruglass, L.M.; Miele, G.M.; Hien, D.A.; Campbell, A.N.; Hu, M.C.; Caldeira, N.; Jiang, H.; Litt, L.; Killeen, T.; Hatch-Maillette, M.; **Najavits, L.M.**; Brown, C.; Robinson, J.A.; Brigham, G.S.; Nunes, E.V. (2012). Helping Alliance, Retention, and Treatment Outcomes: A Secondary Analysis From the NIDA Clinical Trials Network Women and Trauma Study. *Subst Use Misuse*, 47 (6), 695-707.

Najavits, L. M. and Walsh, M. (2012). Dissociation, PTSD, and substance abuse: An empirical study, *Journal of Trauma and Dissociation*.13:1, 115-126
[<http://dx.doi.org/10.1080/15299732.2011.608781>]

Najavits LM. (2012). Expanding the boundaries of PTSD treatment. *JAMA*; 308(7):714-6.

Miller, N.A. & **Najavits, L.M.** (2012). Creating trauma-informed correctional care: A balance of goals and environment. *European Journal of Psychotraumatology*, 3, 1-8.
DOI: 10.3402/ejpt.v3i0.17246

Najavits, L.M. and **Capezza, N.M.** (in press). *Depression and PTSD Comorbidity*, in *The Oxford Handbook of Depression and Comorbidity*, S. Richards and M. O'Hara, Editors. in press, Oxford University Press.

Najavits, L., Highley, J., Dolan, S., & Fee, F. (2012). Substance use disorder, PTSD, and traumatic brain injury. In J. Vasterling, R. Bryant & T. Keane (Eds.), *PTSD and Mild Traumatic Brain Injury*. New York: Guilford Press.

Najavits, L.M. (2012). PTSD / substance use disorder comorbidity treatment: Principles and practices in real-world settings. *Trauma Therapy in Context: The Science and Craft of Evidence-based Practice*. McMackin, B., Newman, E., Fogler, J., Keane, T. Washington, DC, American Psychological Association Press.

Najavits, L.M. (2012). Proximal influences on addiction. In H.J. Shaffer, D. LaPlante & S. Nelson (Eds.), American Psychological Association's addiction syndrome handbook. Washington, DC: American Psychological Association.

Najavits, L.M. (in press). Creating Change: A New Past-Focused Model for PTSD and Substance Abuse. In P. Ouimette & J. P. Read (Eds.), *Handbook of Trauma, PTSD and Substance Use Disorder Comorbidity*. Washington, DC: American Psychological Association Press.

Silverman, B. C., **Najavits, L. M.**, & Weiss, R. D. (in press). Co-Occurring Substance Use Disorders and Other Psychiatric Disorders. In R. J. Frances, S. I. Miller & Mack (Eds.), *Clinical Textbook of Addictive Disorders* (3rd ed., pp. 271-302). New York: Guilford.

Beck, J. S., Liese, B. S., & **Najavits, L. M.** (in press). Cognitive-behavioral therapy. In R. J. Frances, S. I. Miller & A. Mack (Eds.), *Clinical textbook of addictive disorders* (3rd ed., pp. 474-501). New York: Guilford Press.

Najavits, L., Smylie, D., Johnson, K., **Lung, J.**, Gallop, R., & Classen, C. (in press). Seeking Safety therapy for pathological gambling and PTSD: A pilot outcome study. *Journal of Psychoactive Drugs*.

New professional presentations

Dr. Najavits has presented at over 25 professional entities in the current reporting period, on PTSD/SUD and Seeking Safety. A complete list is on her website www.seekingsafety.org.

WRNMMC

A poster on current achievements of the study has been submitted for review and approval by the WRNMMC IRB. If approved, the poster will be presented at the WRNMMC Partial Hospitalization Program & Addiction Treatment Services Program

“Innovative Treatments in Military Behavioral Healthcare” Conference on 5 November 2012.

KEY RESEARCH ACCOMPLISHMENTS:

Details are provided above; requested bulleted list with key accomplishments is here:

- Continued to hire and trained key personnel and study staff, replacing staff as needed. We have an outstanding team at each location, have ongoing communication with all sites, and work effectively across sites.
- Continue to make substantial progress on IRB approvals
- Trained all study clinicians, and have been conducting regular ongoing consultation calls with them to improve their conduct of SS.
- Have been developing the military monograph.
- Made the project more efficient by having one trainer/consultant (Dr. Schmitz) for all sites
- Dropped Fort Jackson as a site as the site PI let us know that due to changes in her role there, she no longer had access to the necessary substance abuse clinicians for this project.
- Dr. Najavits has had a strong record of publications and presentations relevant to the project content (e.g., PTSD, SUD)
- Applied for and obtained a no-cost extension for the study (1 year). We are confident that we can achieve the original scientific aims of the project with this extension.

REPORTABLE OUTCOMES

Not applicable at this point.

CONCLUSION

We have continued to make major progress on all study aims that we could possibly do while still awaiting final IRB and HRPO approval. We are an excellent working team and sites and are confident that with the newly-granted no-cost extension of one year, we will be able to meet all of the scientific aims of this project.

REFERENCES

Not applicable